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Washington DC 20004-1008

In Re: Patent Term Extension
Application for
U.S. Patent No. Re. 36,755

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. Re. 36,755, which claims the human biological product ENBREL® (etanercept), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 230 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 230 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of May 28, 2002 (67 Fed. Reg. 36897). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,143 - 2,041) + 179 \\ &= 230 \text{ days}\end{aligned}$$

Since the regulatory review period began June 26, 1992, before the patent issued (the issue date of the original patent, U.S. Patent No. 5,712,155 was January 27, 1998), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From June 26, 1992 to January 27, 1998 is 2,041 days; this period is subtracted for the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:

Re. 36,755

Granted:

June 27, 2000

Original Expiration Date¹:

March 7, 2012 (terminal disclaimer)

¹Subject to the provisions of 35 U.S.C. § 41(b).

Applicant: Craig A. Smith, et al.
Owner of Record: Immunex Corporation
Title: DNA Encoding Tumor Necrosis Factor - α and - β Receptors
Classification: 435/69.1
Product Trade Name: ENBREL® (etanercept)
Term Extended: 230 days
Expiration Date: October 23, 2012

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Mail Stop Patent Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (703) 872-9411
Attn: Office of Patent Legal Administration

Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.

KF

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: ENBREL® (etanercept)
FDA Docket No. : 99E-1086